20. (NEW) A vaccinating composition containing an immunogenic composition wherein the composition is obtained by the process of claim 16.

21. (NEW) A method of treating a eukaryotic host suffering from a viral pathology comprising administering two polynucleotides, wherein the first polynucleotide codes for the entire virus genome or a part of the virus genome and the second polynucleotide is an insert that expresses a polynucleotide coding for a viral envelope, a part of the envelope, or a surface protein of the viral envelope, wherein both polynucleotides are expressed under the control of a promoter and express viral particles that are selected for fusogenic, non-replicative properties, and for the ability to induce a cytotoxic response through a CMH-1 restricted exogenous antigen presentation pathway.

- 22. (NEW) The method of claim 21, wherein the two polynucleotides are on separate plasmids.
- 23. (NEW) The method of claim 21, wherein the two polynucleotides are on the same plasmid.

REMARKS

Entry of this Preliminary Amendment is respectfully requested prior to examination. The amendments to the claims allow the claims to conform to United States patent practice and do not add new matter.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

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Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: May 20, 2002

Kenneth J. Meyers Reg. No. 25,146

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Appendix to the Amendment of May 20, 2002

IN THE CLAIMS

Please amend the claims as follows:

- 1. (AMENDED) An immunogenic composition capable of inducing a cytotoxic response *in vitro* or *in vivo* against a viral disease through [a] <u>an</u> MHC-1 restricted exogenous antigen presentation pathway without requiring viral replication, [containing] <u>comprising</u> at least one of the compounds:
- (A) a first plasmid [containing] <u>comprising</u> a polynucleotide corresponding to the entire or a part of the viral genome and a second plasmid comprising [in] an insert [containing] <u>of</u> a polynucleotide coding for a viral envelope, [(]a part of the envelope, or a surface protein,[) and being] <u>wherein both plasmids are under</u> the control of a promoter, [said] <u>and the plasmids [being] are selected for their fusogenic properties when binding to antigen presentation cells[,] and for inducing a cytotoxic response through [a] <u>an MHC-1 restricted exogenous antigen presentation pathway;</u></u>
- (B) a plasmid comprising a polynucleotide coding for the entire or a part of the virus genome and [contains] an insert [containing] comprising a polynucleotide coding for a viral envelope, [(or] a part of the envelope, or a surface protein[)], [and being] wherein the plasmid is under the control of a promoter, [said] and the plasmid [expressing] expresses viral particles being selected for their fusogenic non-replicative properties, and for inducing a cytotoxic response afer a CMH-2 restricted exogenous antigen presentation pathway;
- (C) a virus with intact fusogenic capacities, [but whose] wherein the infectious capacities of the virus have been inactivated or attenuated; and,

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- (D) viral particles obtained by the purification of a cell culture supernatant.
- 2. (AMENDED) An immunogenic composition [according to] as claimed in claim 1 wherein the viral particles obtained by the purification of a cell culture supernatant are prepared by transfecting producing cells [(for example, HeLa, 293)] with the plasmids [according to claim 1] in (A) or (B) and purifying the supernatant, or by infecting antigen presenting cells with an HIV virus, purifying the supernatant, and inactivating or attenuating the infectious capacity of the virus.
- 3. (AMENDED) A vaccinating composition [containing] <u>comprising</u> the immunogenic composition [according to] <u>as claimed in</u> claim 2 [in association with] <u>and</u> a pharmaceutically acceptable vehicle.
- 4. (AMENDED) A vaccinating composition [containing] <u>comprising</u> the immunogenic composition [according to] <u>as claimed in</u> claim 2 [in association with] <u>and</u> another vaccine.
- 8. (AMENDED) A [process] method of treatment according to claim [6 or 7] 21, wherein the virus is [an] a human or animal retrovirus.
- 9. (AMENDED) A [process] <u>method</u> of treatment according to claim [6 or 7] <u>21</u>, wherein the virus is HIV-1, HIV-2, SIV, FeLV, or FIV.
- 10. (AMENDED) A [process] <u>method</u> of treatment according to claim [6 or 7] <u>21</u>, wherein [that] the host is a mammal.
- 11. (AMENDED) A [process] <u>method</u> of treatment according to claim [6 or 7] <u>21</u>, wherein the host is a mouse.

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- 12. (AMENDED) A process of stimulation *in vivo* of cytotoxic lymphocytes through an MHC-1 restricted exogenous antigen presentation pathway without requiring viral replication, comprising:
- (A) [administration of the] <u>administering</u> [plasmids contained in the immunogenic composition according to claims] <u>an immunogenic composition as claimed in claim</u> 1 [or 2] to [the host according to claim 10] <u>a mammal</u>;
- (B) optionally <u>testing [the]</u> cytotoxic T cells obtained <u>from the mammal after</u> [the] step (A) [A above are tested] in a cytotoxic test comprising:
 - (i) [the incubation of] incubating an organ or a biologic fluid of the host, wherein the organ or biologic fluid contains [containing] cytotoxic T cells [of] from the host with a synthetic peptide, [which] wherein the sequence of the synthetic peptide is encoded by a viral genome contained partly in the first or the second plasmid; or
 - (ii) [the use of] <u>incubating the</u> target cells with the same HLA haplotype as the host or a compatible HLA haplotype, said target cell being incubated with a synthetic peptide, [which] <u>wherein the synthetic peptide has a sequence that is a part of the sequence of an HIV- genome.</u>
- 15. (AMENDED) A process of treatment of an eukaryotic host suffering from a viral pathology, [wherein] comprising treating and incubating antigen presenting cells [are treated] with the immunogenic composition [of claims] as claimed in claim 1 [to 4 then administrated] and administering the antigen presenting cells back to the mammal after incubation.

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16. (AMENDED) A process of screening a composition[, which] that is capable of [inducing against a viral pathology] a cytotoxic response in response to a viral pathology in vitro or in vivo by exogenous antigen presentation without viral replication, comprising [the cytotoxic activity of said composition is determined by the process according to claims 12 to 14]

- (A) <u>administering an immunogenic composition as claimed in claim 1 to a</u>

 mammal;
- (B) testing cytotoxic T cells obtained from the mammal after step (A) in a cytotoxic test comprising:
 - (i) incubating an organ or a biologic fluid of the host, wherein the organ or biologic fluid contains cytotoxic T cells from the host, with a synthetic peptide, wherein the sequence of the synthetic peptide is encoded by a viral genome contained partly in the first or the second plasmid; or
 - (ii) incubating the target cells with the same HLA haplotype as the host or a compatible HLA haplotype, said target cell being incubated with a synthetic peptide, [which] wherein the synthetic peptide has a sequence that is a part of the sequence of an HIV- genome.
- 17. (AMENDED) A method of determining <u>a</u> cytotoxic T lymphocyte (CTL) reponse to an antigen, wherein the method comprises:
- (A) providing viral particles containing the antigen and having a fusogenic envelope membrane;
- (B) targeting the viral particles into professional antigen presenting cells (APCs) by binding [of] the viral particles to the plasma membranes of the APCs [and]

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- (C) [uptake of] <u>allowing</u> the viral particles <u>to be taken up</u> by the APCs [following] <u>after</u> fusion of the fusogenic envelope membranes of the viral particles with the plasma membranes of the APCs, [which is]
- (D) [followed by] <u>presenting the antigen by MHC-I-restricted presentation [of the antigen]</u> by the APCs without viral replication or de novo, *in situ* synthesis of the antigen in the APCs;
- (E) contacting the resulting transduced APCs with CTLs that recognize MHC-I-restricted antigen; and
 - (F) determining cell cytotoxicity resulting from said contact.

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